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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,776	02/24/2000	Roger K Craig	4256/86197	5653

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/27/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/511,776

Applicant(s)

CRAIG ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10-14 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4-8 and 10-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 3/24/03 in Paper No. 18 is acknowledged and has been entered. Claims 1, 2, 13, 19, and 20 have been amended. Claims 15-18 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Currently, claims 1, 2, 4-8, and 10-22 are pending. Claims 1, 2, 4-8, 10-14, and 19-22 are under examination.

Rejections Withdrawn

2. In light of Applicant's amendment, the rejection of claims 1, 4-8, 10-14, and 19-22 under 35 U.S.C. 112, first paragraph, is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4-8, and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, is confusing in reciting, "wherein detection of a signal generated by said labeled first binding partner *and/or* labeled second binding partner is an indicator of the conformational state of the protein" because it is unclear how the

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conformational state of the protein is detected or determined when the signal generated is only that of the labeled second binding partner which binds with the protein *independent* of the conformational state of the protein. Please clarify.

Double Patenting

4. Claims 1, 4-8, 10-14 and 19-22 stand provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 and 18-21 of copending Application No. 09/258,452. This provisional double patenting rejection is being maintained for reason of record. (See Paper No. 9).

Note: A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prusiner et al. (US 5,891,641) in view of Foster et al. (US 4,444,879) for reason of record.

Prusiner et al. disclose a method for determining a diseased related conformational state of a protein such as PrP^{Sc} in a sample (see column 5, lines 21-58). Prusiner et al. specifically disclose contacting the protein with a labeled antibody that binds (has a higher binding affinity) to the protein in a manner dependent on the conformational state of the protein; i.e. PrP^C (native or non-disease state) or PrP^{Sc} (diseased conformation) (see column 4, lines 24-56, column 12, lines 4-28, an column 17, lines 49-58). The antibody is detectably labeled with fluorophores, radioisotopes, enzymes, etc. so as to detect labeling of the protein wherein a generation of signal is indicative of the conformational state of the protein (see column 12, lines 64-67). Prusiner et al. also disclose contacting the protein with a second antibody in a sandwich format (see column 16, lines 25-38). Prusiner et al. also disclose that recombinant prion proteins can be covalently linked (chemically crosslinked) to a solid phase substrate (polystyrene plates) (see column 6, lines 1-3). Standard preparations of disease related

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conformational state proteins such as prion proteins are produced for use in calibration and validation testing of the diagnostic sensitivity, specificity and predictive values of the assay (see column 22, lines 58-61). Antibody binding to the disease related conformation is measured using time resolved, dissociation enhanced fluorescence (see column 17, lines 62-65).

Prusiner et al. have been discussed supra. Prusiner et al. differ from the instant invention in failing to incorporate the protein standards, binding partners, labels, and packaging components into a kit format.

Foster et al. disclose controls, reagents including antibodies and labels, and instructions in a kit format for use in assay methods.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have incorporated the protein standards, binding partners and label reagents taught by Prusiner into a kit format as taught by Foster et al., for use in a method of determining the conformational state of a protein because kit formats are recognized for their advantage in convenience and economy.

Response to Arguments

6. Applicant's arguments filed 3/24/03 have been fully considered but they are not persuasive.

A) Applicant argues that the combination of Prusiner et al. with Foster et al. do not suggest the kit of the claimed invention. Applicant specifically argues that Prusiner et al. do not teach a first labeled binding partner which binds to the protein in a manner

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dependent on the conformational state of the protein and a second labeled binding partner that is independent of the conformational state of the protein and generates a signal in a manner dependent on the binding of the first binding partner to the protein. According to Applicant, Foster et al. do not remedy the deficiency of Prusiner et al.; therefore, the combination of Prusiner et al. with Foster et al. does not render the claimed invention, obvious.

In response, Prusiner et al., indeed, additionally teach a second binding partner, i.e. antibody, which binds to the protein depending on the conformational state of the protein, in a sandwich format of an assay (see column 16, lines 25-38).

Additionally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

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Gailene R. Gabel

Patent Examiner

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August 24, 2003

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Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641